REMARKS

In response to the Office Action dated March 20, 2008, the Applicant respectfully requests consideration of the following remarks.

Claims 16-24, 38 and 39 are pending in the current application and were rejected under 35 USC 102(e) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over U.S. Patent No. 4,994,033 to Shockey, *et al.* ("Shockey"). In response to this rejection, the Applicant respectfully submits the following remarks.

Claim 16 recites:

> 16. A process for treating tissue at a treatment site within a body lumen, comprising:
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> providing an elongate flexible catheter having a flexible treatment sheath mounted to a distal end region of the catheter and a dilatation balloon within the flexible treatment sheath, wherein the flexible treatment sheath is formed of an elastic material and the dilatation balloon is formed of a substantially inelastic material;
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> intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a predetermined treatment site;
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> supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact; and
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> while maintaining the treatment sheath in said substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue.

Claims 38 and 39 add the following limitations regarding the treatment sheath:

> 38. The process of claim 16, wherein said treatment sheath is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer.
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> 39. The process of claim 38, wherein the biocompatible elastomeric material has a modulus of elasticity in the range of 2,000 to 80,000 psi, said sheath has a uniform thickness in the range of 0.5-5 mils, whereby the treatment sheath elastically expands into said substantially conforming contact.

The invention as recited in claim 16 clearly sets forth at least two different materials. First, the flexible treatment sheath "is formed of an elastic material." Second, the dilatation balloon "is formed of a substantially inelastic material."

The treatment sheath is elastic and the dilatation balloon is substantially inelastic in order to achieve the goals of the invention set forth in the specification. The treatment sheath is elastic so that it expands "into a substantially conforming contact with surrounding tissue at the treatment site." (Specification, para. 13). "Because of the elasticity of sheath 22, it does not enlarge the artery or otherwise substantially change the shape of the surrounding tissue. Rather, it conforms to the shape and contours of the vessel wall, as seen in FIG. 5." (Specification, para. 52). With respect to the specific materials that can be used for various embodiments of the treatment sheath as recited in dependent claims 38 and 39, the specification states:

> The sheath advantageously is formed of a biocompatible elastomer having a modulus of elasticity in the range of about 2,000 to 80,000 psi, and with a uniform thickness in the range of about 0.5-5 mils. Accordingly, responsive to a low inflation pressure (e.g. about one atmosphere gauge pressure), the sheath readily expands into the desired intimate and conforming contact with tissue. The elasticity is a positive factor in permitting the sheath to stretch in response to encountering tissue surface irregularities.
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> * * *
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> Delivery sheath 22 is formed of an elastic biocompatible polymer, e.g. latex. Other suitable materials include polyurethane, silicone, and thermoplastic elastomers. The thickness of the sheath is determined in view of the selected material, to provide a high degree of stretching of the sheath to conform to the shape and contours of surrounding tissue when sheath 22 is expanded against the tissue. In general, the ability of the sheath to conform to tissue irregularities is a function of the material modulus of elasticity and sheath thickness. Consistent with an adequate tensile strength, lower elastic moduli are preferred. A sheath having a lower modulus of elasticity experiences a greater amount of elastic elongation or "stretch" in response to a given force, i.e. a given fluid pressure of the therapeutic agent in the compartment. In particular, suitable materials will have elastic moduli within a range from about 2,000 psi to about 80,000 psi. Preferred thicknesses are in the range of from about 0.5 mils to about 5 mils.

(Specification, paras. 15, 47 (emphasis added)).

In contrast to the "elastic" treatment sheath, the dilatation balloon inside the sheath is "substantially inelastic," giving it a "non-distensible" property whereby it tends to maintain its shape under increased internal pressure. The specification states:

> Preferably the delivery means comprises an elongate and flexible catheter, with the dilatation means comprising a substantially inelastic and fluid impermeable dilatation balloon.
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> * * *
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> Dilatation balloon 24 preferably is constructed of a polymeric material that is sufficiently pliable or formable to readily achieve an enlarged state, yet is relatively non-distensible, i.e. tending to maintain it shape under increased fluid pressure within the balloon. Nylon is a preferred material for the dilatation balloon. Other suitable materials include PET, polyolefin, polyethylene, polybutylene terepthalate, PVC, polypropylene and their copolymers.

(Specification, paras. 14, 45 (emphasis added)).

As set forth in the specification, these material properties are important to the intended purpose and operation of the invention:

> Several performance advantages arise from the greater elasticity [of the treatment sheath] and resulting conformity to the tissue. First, wall segment 86 and the arterial tissues are contiguous over a much greater surface area. As a result a fluid tight seal is formed over the sheath/tissue interface, preventing blood from contacting tissue that is contiguous with the sheath. The prevention of contact with blood, particularly as to freshly cracked lesions, may considerably reduce the probability of restenosis.
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> Second, the seal enhances concentration of the therapeutic agent along the interface, more specifically that portion of the sheath/tissue interface where pores 56 are formed through the sheath. Improved concentration reduces the amount of the agent needed for effective treatment, and reduces potential toxicity concerns.
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> Third, the fluid tight seal effectively isolates the therapeutic agent and blood from one another, preventing the loss of efficacy in certain agents caused by contact with blood.
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> With the delivery sheath and tissue contiguous over a much greater proportion of their interface as in FIG. 9, the therapeutic agent perfuses through pores 56 directly into tissue, as opposed to merely perfusing into gaps between the balloon and tissue as would be the case in FIG. 8. The result is a more uniform application of the therapeutic agent to tissue under treatment. Finally, on a larger scale than that depicted in FIGS. 8 and 9, the elastic delivery sheath can conform to non-cylindrical arterial

> passageways, for example in regions of the coronary artery with collateral arteries, branching or eccentric lesions. The highly flexible delivery sheath can establish fluid tight seals in such areas, where the conventional non-distensible balloon does not "fit".

(Specification, paras. 59-62 (emphasis added)).

The meaning of the claim language is clear as to the requirement of the different materials. First, the claim language states that the treatment sheath is formed of an "elastic" material and the dilatation balloon is formed of a "substantially inelastic" material. The elasticity of a material is a mechanical property that can be quantified and is typically expressed as the "modulus of elasticity." Materials with a higher "modulus of elasticity" are less elastic. From the claim language, the treatment sheath must have a lower modulus of elasticity so that it is "elastic," and the dilatation balloon must have a substantially higher modulus of elasticity so that it is "substantially inelastic."

Second, the specification makes clear that the treatment sheath is formed of an "elastic" material and the dilatation balloon is formed of a "substantially inelastic" material in order to have the device function in a specific manner. As described above, the treatment sheath is elastic in order to conform to irregularities in the vessel wall for the delivery of the treatment fluid. By contrast, the dilatation balloon is substantially inelastic to effect a dilatation of the surrounding tissue. As would be understood by persons of ordinary skill in the art, substantially inelastic dilatation balloons allow the physician to introduce high pressure forces in the balloon without causing the balloon to expand excessively, thereby allowing the balloon to exert high forces on the vessel wall to effect a dilatation without causing undesirable damage to the vessel.

Third, a person of ordinary skill in the art would understand what materials could be used to achieve the described "elastic" treatment sheath and the "substantially inelastic" dilatation balloon. For the treatment sheath, the specification states that the sheath may be formed, for example, of "an elastic biocompatible polymer, e.g. latex." The specification states that the elastic material may have "a modulus of elasticity in the range of about 2,000 to 80,000 psi." (Specification, paras. 15, 47). For the dilatation balloon, the specification lists possible materials, including, for example, "nylon" and other materials that can be selected as "substantially inelastic" materials. (Specification, paras. 14, 45).

For reference, attached is a table showing the modulus of elasticity of various materials. For comparison, the modulus of elasticity of rubber and nylon are shown below:

Material	Modulus of Elasticity (psi)
Rubber	1,450 – 14,500[1]
Nylon	290,000 – 580,000[2]

A person of ordinary skill in the art would plainly understand, from Applicant's disclosure, that a material such as rubber or latex with a relatively low modulus of elasticity is "elastic" within the meaning of Applicant's disclosure, and a material such as nylon or another material with a relatively high modulus of elasticity as compared to the elastic material of the treatment sheath is "substantially inelastic" within the meaning of Applicant's disclosure.

The Shockey Device

In contrast to Applicant's invention, the Shockey reference does not disclose using different materials for the inner and outer members, much less different materials as claimed in the Applicant's claims. Shockey discloses an expander member 22 and an inner sleeve 30. Shockey does not state, suggest or even hint at making the expander member 22 and the inner sleeve 30 of different materials, much less making the expander member 22 and the inner sleeve 30 of different materials such that the expander member can be fairly characterized as "elastic" in comparison to a substantially inelastic inner sleeve.

Request for Reconsideration

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Because Shockey does not disclose a treatment sheath "formed of an elastic material" in combination with a dilatation balloon "formed of a substantially inelastic material," the Applicant respectfully requests withdrawal of the anticipation rejection.

To sustain a rejection based on obvious, there must be "an apparent reason to combine the known elements in the fashion claimed" in the claims at issue. *KSR International Co. v.*

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[1] The modulus of elasticity of rubber is listed as 0.01×10^9 N/m^2 – 0.1×10^9 N/m^2, which is approximately 1,450 psi – 14,500 psi (using a conversion of 1 N/m^2 = 1.45×10^{-4} psi).

[2] The modulus of elasticity of nylon is listed as 2×10^9 N/m^2 - 4×10^9 N/m^2, which is approximately 290,000 psi – 580,000 psi (using a conversion of 1 N/m^2 = 1.45×10^{-4} psi).

Teleflex Inc., 550 U.S. 1, 14, 82 USPQ2d 1385 (2007). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Here, Shockey does not disclose or suggest different materials for the inner and outer members, much less an outer member that is "elastic" as compared to a substantially inelastic inner member. The only "reason" for modifying Shockey to arrive at Applicant's claims is through the use of Applicant's own teachings, which is not proper in an obviousness analysis. This is not simply a case of "optimizing" the inner and outer members of Shockey, because nothing in Shockey or elsewhere in the art suggests or even hints that Shockey's inner and outer members should be different from each other. Thus, arriving an Applicant's claims is not simply a matter of adjusting Shockey. Instead, Applicant has invented a novel and nonobvious device which has a treatment sheath which is elastic and a dilatation balloon which, by contrast, is substantially inelastic, in order to achieve the significant advantages that are described in Applicant's specification but not found in or suggested by Shockey or any of the other prior art of record.

In view of the foregoing, the Applicant respectfully requests favorable reconsideration of this application and allowance of all claims. Should any questions arise, the Examiner is invited to call the undersigned at the number given below. The Commissioner is hereby authorized to charge any fees and credit any overpayments associated with this filing to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

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